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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,849	08/22/2002	Helen Allison	38-21(52179)B	3130

27161 7590 07/27/2006

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EXAMINER	
PAGE, BRENT T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/064,849	ALLISON ET AL.	
	Examiner	Art Unit	
	Brent Page	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *5-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/25/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS 02/19/2003*.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-4 in the reply filed on 05/02/2006 is acknowledged. The traversal is on the ground(s) that the other Groups do not present a serious search burden to the Examiner. This is not found persuasive because a search of the Invention of Group I would not be sufficient to search the alternate media components and conditions of the other Groups.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The embedded hyperlink is found in paragraph 52 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to an optimized method of transforming any monocotyledonous plant using tissue culture.

In contrast, the specification only provides guidance to optimized agrobacterium transformation of wheat using tissue culture, and does not provide guidance for conditions that would improve the transformation efficiency of any other monocotyledonous plant.

The optimization of transformation with agrobacterium using tissue culture is species specific, and therefore unpredictable. In a review on plant transformation, Hansen et al (1999 Trends in Plant Science 4:226-231) discuss the variability of different plant species with respect to *Agrobacterium*-mediated transformation. Hansen et al state "Because of having to deal with two different biological elements, many parameters should be tested to satisfy both partners and guarantee a successful outcome" (see page 228, second column end of third paragraph". Hansen et al further state "Some crops appear to react, or be hypersensitive, to *Agrobacterium* inoculation by forming necrotic barriers" (see page 228 second column beginning of final paragraph).

Furthermore, Potrykus (1990 Biotechnology 8(6): 535-542) details the unpredictability inherent in plant transformation and maintenance of the exogenous DNA in plants as generally claimed, particularly in monocots. Potrykus (1990), reviewing gene transfer to cereal plants (monocots), teaches the general recalcitrance of monocots to transformation; and discusses the

variability relating to gene transfer, considers the biology of gene transfer, saying that "a transgenic plant can only result from integrative transformation in a totipotent cell or a cell that has a clonal connection to the 'germline'". Issues of concern here are "(1) Not all plant cells are totipotent. (2) Plant cells differ in their capacity to respond to triggers, a phenomenon termed *competence*. (3) Cells from which it is hoped to regenerate transgenic plants must be competent for both regeneration (in a broad sense) and integrative transformation. (4) Plant tissues are composed of cells competent for many different responses. Considering the two states of competence essential for recovery of transgenic plants the following situation has to be considered: a/ A very small minority of cells in plant tissues will be competent for both transformation and regeneration. b/ Others will be competent for transformation or regeneration. c/ A large fraction of the cell population will be potentially competent, meaning that given the correct treatment they will have the potential to shift to the competent state. d/ A variable proportion of cells will not even be potentially competent, but will be non-competent. (5) The relative composition of cell population in tissues is determined by the genotype, the type of organ, the developmental state of the organ, and even the individual history of the experimental plant" (p. 538, column 1, bottom ¶). Of 23 different plant transformation techniques, only two, direct gene transfer into protoplasts and microprojectile bombardment, have shown any promise in either producing transformed monocot cells, whole transformed monocot plants, or transformed offspring (see pages 536-537).

Given the state of the art, the disclosures by Hansen and Potrykus, and the unpredictability of the species-specific nature of Agrobacterium-mediated transformation, as discussed by Hansen et al and Potrykus, it would be undue experimentation to evaluate all monocotyledonous plants for their transformation efficiencies with all media concentrations disclosed as broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are drawn to a method for transforming a monocotyledonous plant wherein a first medium contains increased MS salts from between "about" 1.5 times standard to "about" 3 times standard and a concentration of picloram from between "about" 2.5 mg/L to "about" 5 mg/L.

The term "about" is not defined by any examples or otherwise in the specification to give any guidance as to the range of numbers around the stated endpoints. With an indefinite range of numbers, "about" 1.5 times standard, is interpreted to read on standard conditions, as well as reduced salt concentrations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (1997 Plant Physiology 115:971-980) in view of Barro et al (1999 Euphytica 108:161-167).

The claims are drawn to a method for transforming a monocotyledonous plant using an Agrobacterium-mediated process comprising preculturing an immature embryo in a first medium containing increased MS salts from about 1.5 times standard to about 3 times standard and a concentration of picloram from between about 2.5 mg/L to about 5 mg/L, contacting the precultured embryo with Agrobacterium, co-cultivating the precultured embryo with Agrobacterium and regenerating plants expressing a genetic construct, wherein the embryo is cultured in a second medium containing a selective agent, and wherein the monocotyledonous plant is wheat. For examination purposes the language "about 1.5" is interpreted to read on 1.0 or even amounts less than 1.0.

Cheng et al teach a method for transforming wheat using an Agrobacterium-mediated process comprising preculturing immature embryos with full strength MS salt which is considered to be "about" 1.5 times standard concentration, wherein the embryo is co-cultivated with Agrobacterium and then cultured in a second medium containing carbenicillin for selection, and plants were regenerating exhibiting resistance to carbenicillin (see page 972 in its

entirety, for example). Cheng et al state "The salt strength in the inoculation medium was also found to influence the T-DNA delivery".

Cheng et al do not teach preculturing immature wheat embryos with picloram.

Barro et al teach preculturing immature wheat embryos with 4 mg/L picloram (see page 163, last paragraph, and page 164 first four paragraphs, for example). Barro et al state "In the present experiments, we found that picloram in the induction medium gave rise to more regenerative cultures than 2,4-D" (see page 166 first full paragraph).

Given the state of the art, and the disclosures by Cheng et al and Barro et al it would have been obvious to one of ordinary skill in the art to preculture the immature embryos taught by Cheng et al with picloram as taught by Barro et al, and suggest by Barro et al. Should the claims be interpreted in such a way that the method described above requires an increase of MS salt concentration in the preculturing of the immature embryos to double standard strength, it would have further been obvious to one of ordinary skill in the art to modify the method described by Cheng et al by increasing the concentration of MS salts as suggested by Cheng et al considering that the salt concentration was shown to affect the transformation efficiency by Cheng et al.

No Claims are free of the prior art.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638